

## Message Text

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ORIGIN HEW-06

INFO OCT-01 AF-06 ARA-10 ISO-00 OES-05 EB-07 COME-00 /035 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.: AMS

APPROVED BY OES/APT/BMP: WJWALSH, III

DHEW/OIH: MACODDING

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P 152318Z MAR 76

FM SECSTATE WASHDC

TO AMEMBASSY BOGOTA PRIORITY

AMEMBASSY SAN JOSE PRIORITY

AMEMBASSY MEXICO PRIORITY

AMEMBASSY CARACAS PRIORITY

AMCONSUL RIO DE JANEIRO PRIORITY

AMCONSUL CAPE TOWN PRIORITY

INFO AMEMBASSY BRASILIA PRIORITY

AMEMBASSY PRETORIA PRIORITY

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E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, BR, CO, CS, MX, SF, VE

SUBJECT: FDA ADVISORY - DEFECTIVE PACKAGING OF  
ANGIOGRAPHIC CATHETER (RECALL T-069-6)

1. FDA ADVISES OF THE FOLLOWING RECALL:

PRODUCT INVOLVED: CORDIS DUCOR BRAND ANGIOGRAPHIC  
CATHETERS. EACH CATHETER IS PACKAGED IN A TWO LAYER  
ENVELOPE WHICH IS A MYLAR PLASTIC TOP BONDED TO A TYVEK  
PAPER BOTTOM, ENVELOPES LABELED IN PART "STERILE X NON-  
PYROGENIC X MUST BE STERILE WHEN USED X CORDIS CORPORATION,  
MIAMI, FLA. XX". THE CATHETERS ARE PACKED 5 TO A BOX.  
THE BOX IS SIMILARLY LABELED.

LOT NUMBERS: ALL CATALOG NUMBERS AND LOT NUMBERS OF  
CATHETERS PACKAGED ON THE ROTOWRAP HEAT SEAL MACHINE IN  
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CORDIS PLANT NO. 3 BETWEEN THE DATES OF 9/29/75 AND

10/2/75, ARE UNDER RECALL. THE LOTS (29) ARE AS FOLLOWS:

CATALOG NUMBER	LOT NUMBER
523-750	3095404, 3095416, 3105019
523-850	3095405, 3095417

CATALOG NUMBER	LOT NUMBER
523-760	3095406
522-732	3095407
521-745	3095408
525-783	3095409
523-841	3095410, 3105012
523-716	3095411, 3095415, 3105006
523-843	3095412, 3095413
525-782	3095414
523-840	3095418, 3095419
523-842	3105001, 3105014
525-881	3105003
523-762	3105004
521-845	3105013
523-721	3105015
521-732	3105016
523-740	3105017
523-715	3105018
523-852	3105020

MANUFACTURER/RECALLING FIRM:

CORDIS CORPORATION PLANT NO. 3  
3915 BISCAYNE BLVD.  
MIAMI, FLORIDA 33137

2. REASON FOR ADVISORY (RECALL): DURING FIELD EXAMINATION OF CORDIS CATHETERS, IT WAS NOTED THAT AN UNKNOWN OBJECT HAD PUNCTURED THE SEALED ENVELOPE, FORMING A PINHOLE AND BREAKING THE STERILE SEAL. ALL LOTS INVOLVED WERE HEAT SEALED ON THE SAME ROTOWRAP MACHINE IN THE FIRM'S PLANT NO. 3. THE FIRM CONJECTURES THAT A PIECE UNCLASSIFIED

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OF METAL FILING OR OTHER DEBRIS BECAME IMBEDDED IN THE COMPRESSION HEAD OF THE MACHINE AND WHEN COMPRESSED, RESULTED IN PUNCHING A SMALL HOLE IN EACH CATHETER ENVELOPE PASSING THROUGH THE MACHINE. THE DEFECT WAS NOT NOTICED PRIOR TO DISTRIBUTION.

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO

DETERMINE IF THEY HAVE RECEIVED RECALL LETTER DATED  
2/13/76 REQUESTING CONSIGNEES TO RECOVER UNUSED CATHETERS  
OF SUSPECT LOTS AND DESTROY THEM OR RETURN THEM TO FIRM  
FOR REPROCESSING. ANY QUESTIONS CONSIGNEES MAY HAVE  
REGARDING THE RECALL SHOULD BE DIRECTED TO FIRM.

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4. FOREIGN CONSIGNEES AS FOLLOWS:

NAME AND ADDRESS	LOT NO.	CAT. NO.	NO. SHIPPED
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IMPORTACAO MEDICA COR LTDA. RUA SENADOR DANTAS 76 SOBRELOJAS RIO DE JANEIRO, BRASIL	3105004	523-762	10
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SOCIEDAD IMPORTADORA GRASSI RUA SENADOR DANTAS 76 SOBRELOJA RIO DE JANEIRO, BRASIL	3105017	523-740	5
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MAX MEYER APARTADO AEREO 12220 BOGOTA, COLOMBIA	3105017	523-740	5
	3105015	523-721	5
	3095404	523-750	5

COSTA RICA DENTAL AND MEDICAL SUPPLY COMPANY APARTADO NO. 434 SAN JOSE, COSTA RICA	3105004	523-762	10
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MEDICINA TECNICA S.A. ALVARO OBREGON 242 -4 PISO MEXICO CITY, D.F.	3105017	523-740	10
	3095416	523-760	5
	3105015	523-721	20
	3095404	523-750	20

EQUILAB C.A. APARTADO NO. 60497 CARACAS 106, VENEZUELA	3095404	523-750	15
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MESSRS. FREDERIC MARCUS AND COMPANY BOX 3039 CAPETOWN	3105017	523-740	5
	3095412	523-843	25
	3095408	521-745	30
	3105-04	523-761	10 KISSINGER

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## Message Attributes

**Automatic Decaptioning:** X  
**Capture Date:** 01 JAN 1994  
**Channel Indicators:** n/a  
**Current Classification:** UNCLASSIFIED  
**Concepts:** MEDICAL CARE, EQUIPMENT, COMMODITIES, THREATS  
**Control Number:** n/a  
**Copy:** SINGLE  
**Draft Date:** 15 MAR 1976  
**Decaption Date:** 01 JAN 1960  
**Decaption Note:**  
**Disposition Action:** n/a  
**Disposition Approved on Date:**  
**Disposition Authority:** n/a  
**Disposition Case Number:** n/a  
**Disposition Comment:**  
**Disposition Date:** 01 JAN 1960  
**Disposition Event:**  
**Disposition History:** n/a  
**Disposition Reason:**  
**Disposition Remarks:**  
**Document Number:** 1976STATE062690  
**Document Source:** CORE  
**Document Unique ID:** 00  
**Drafter:** JRWEINROTH, M.D.: AMS  
**Enclosure:** n/a  
**Executive Order:** N/A  
**Errors:** N/A  
**Film Number:** D760097-0896  
**From:** STATE  
**Handling Restrictions:** n/a  
**Image Path:**  
**ISecure:** 1  
**Legacy Key:** link1976/newtext/t19760359/aaaabzzu.tel  
**Line Count:** 168  
**Locator:** TEXT ON-LINE, ON MICROFILM  
**Office:** ORIGIN HEW  
**Original Classification:** UNCLASSIFIED  
**Original Handling Restrictions:** n/a  
**Original Previous Classification:** n/a  
**Original Previous Handling Restrictions:** n/a  
**Page Count:** 4  
**Previous Channel Indicators:** n/a  
**Previous Classification:** n/a  
**Previous Handling Restrictions:** n/a  
**Reference:** n/a  
**Review Action:** RELEASED, APPROVED  
**Review Authority:** wolfsd  
**Review Comment:** n/a  
**Review Content Flags:**  
**Review Date:** 01 JUL 2004  
**Review Event:**  
**Review Exemptions:** n/a  
**Review History:** RELEASED <01 JUL 2004 by vandyklc>; APPROVED <01 SEP 2004 by wolfsd>  
**Review Markings:**

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US Department of State  
EO Systematic Review  
04 MAY 2006

**Review Media Identifier:**  
**Review Referrals:** n/a  
**Review Release Date:** n/a  
**Review Release Event:** n/a  
**Review Transfer Date:**  
**Review Withdrawn Fields:** n/a  
**Secure:** OPEN  
**Status:** NATIVE  
**Subject:** FDA ADVISORY - DEFECTIVE PACKAGING OF ANGIOGRAPHIC CATHETER (RECALL T-069-6)  
**TAGS:** OGEN, ETRD, TBIO, BR, CO, CS, MX, SF, VE  
**To:** BOGOTA MULTIPLE  
**Type:** TE  
**Markings:** Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 04 MAY 2006